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Evaluation Report ERC2012-03

Whole Egg Solids, Wintergreen Oil, Castrol Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids

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Table of Contents

Overview 1
Registration Decision for Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids 1
What Does Health Canada Consider When Making a Registration Decision? 1
What Are Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture Capsaicin and Related Capsaicinoids? 2
Health Considerations 2
Environmental Considerations 3
Value Considerations 4
Measures to Minimize Risk 4
What Additional Scientific Information Is Being Requested? 5
Other Information 5
Science Evaluation 7
1.0 The Active Ingredient, Its Properties and Uses 7
1.1 Identity of the Active Ingredient 7
1.1.1 Whole Egg Solids 7
1.1.2 Bobbex Deer Repellent RTU Technical 7
1.1.3 Bobbex Deer Repellent Concentrate Technical 8
1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product 9
1.2.1 Technical Product: Dried Whole Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical 9
1.2.2 End-Use Product: Bobbex Deer Repellent Concentrate, Bobbex Deer Repellent Ready-To-Use Spray 10
1.3 Directions for Use 11
1.4 Mode of Action 11
2.0 Methods of Analysis 12
2.1 Methods for Analysis of the Active Ingredient 12
2.2 Method for Formulation Analysis 12
3.0 Impact on Human and Animal Health 12
3.1 Integrated Toxicology Summary 12
3.2 Occupational/Residential Exposure and Risk Assessment 13
3.2.1 Occupational/Domestic-user 13
3.2.2 Bystander 14
3.3 Food Residue Exposure Assessment 14
3.4 Aggregate Exposure 14
4.0 Impact on the Environment 14
4.1 Fate and Behaviour in the Environment 14
4.2 Environmental Risk Characterization 15
5.0 Value 15
5.1 Effectiveness Against Pests 15
5.1.1 Acceptable Efficacy Claims 15
5.2 Phytotoxicity to Host Plants 15
5.2.1 Acceptable Claims for Host Plants 15
5.3 Sustainability 16

5.3.1 Survey of Alternatives 16
5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management 16
5.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance 16
6.0 Pest Control Product Policy Considerations 16
6.1 Toxic Substances Management Policy Considerations 16
6.2 Formulants and Contaminants of Health or Environmental Concern 17
7.0 Summary 18
7.1 Human Health and Safety 18
7.2 Environmental Risk 18
7.3 Value 18
7.4 Unsupported Uses 18
8.0 Regulatory Decision 19
Appendix I Tables and Figures 23
Table 1 Acute Toxicity of Technical Products Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil and Meat Meal Mixture and the Associated End-use Products (Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray) 23
Table 2 Toxicity Profile of Technical Whole Egg Solids 24
Table 3 Toxicity Profile of Technical Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil and Meat Meal Mixture 25
References 27

Overview

Registration Decision for Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Dried Whole Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray containing the active ingredients Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids to prevent feeding damage to outdoor ornamental plants by white-tailed deer and black-tailed deer.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk reduction measures are followed, the applicant must submit additional scientific information as a condition of registration.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Dried Whole Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Are Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids?

Whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids prevents feeding damage to outdoor ornamentals by combining both odour and taste repellents.

Health Considerations

Can Approved Uses of Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and related Capsaicinoids Affect Human Health?

Whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids are unlikely to affect your health when used according to label directions.

Exposure to whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids may occur when handling and applying the products, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray, as well as during typical residential activities following application. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Eggs, fish, and garlic are known to cause allergic reactions in sensitive individuals. Precautionary statements alerting users of the potential for an allergic reaction in individuals sensitive to eggs, fish, and garlic are required on the product labels for both Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray.

Inhalation, dermal, and ocular exposures are possible when applying the product, particularly to the applicator and bystanders located near the treatment area. Also, entry into a recently sprayed area may result in dermal exposure. Therefore, spray advisory and restricted entry statements are required on the end-use product labels to minimize applicator and bystander exposures.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The use pattern of Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray do not include food or feed crops. The active ingredients are found in foods and consumer products and any residues that may occur in drinking water from the use pattern are not expected to pose a concern to human health.

Occupational Risks from Handling Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray

Occupational risks are not of concern when Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray are used according to label directions, which include protective measures.

Domestic users handling and applying Bobbex Deer Repellent Concentrate or Bobbex Deer Repellent Ready-To-Use Spray to areas that attract deer, such as trees, plants, shrubs, flowers, and non-flowering plants, can come in direct contact with the active ingredients on the skin and in the eyes. Following the precautionary label statements aimed at minimizing exposure to the product will ensure domestic users are appropriately protected. The potential for inhalation while handling and applying the product will be negligible when users observe the precautionary label statements.

Accidental bystander exposure is possible from spray drift, but exposure is expected to be negligible when the precautionary label statements are observed by the applicator.

Postapplication exposure is possible in individuals who immediately enter freshly treated areas. People who are allergic to eggs, fish or garlic should exercise precaution before entering freshly treated areas.

Environmental Considerations

What Happens When Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids are Introduced Into the Environment?

Whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids are expected to degrade rapidly in the environment. The active ingredients are food grade, and have a non-toxic mode of action, i.e. they act as a repellent. Environmental exposure is expected to be minimal when the end-use products containing these active ingredients are used under the current domestic use pattern.

Value Considerations

What Is the Value of Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray?

Bobbex Deer Repellent Concentrate applied at a dilution of 1 part product to 5 parts water and Bobbex Deer Repellent Ready-To-Use prevents feeding damage to outdoor ornamentals by white-tailed and black-tailed deer by combining both odour and taste repellents.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Dried Whole Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray to address the potential risks are as follows.

Key Risk-Reduction Measures

Human Health

The statement, "Warning, contains the allergen egg", has been included on the principal display panel of the technical product label for Dried Whole Eggs and "Warning, contains the allergen fish" on the principal display panel of the technical product labels for each of the technical products. The statements, "DANGER – EYE IRRITANT", "CAUTION – SKIN IRRITANT", "POTENTIAL SENSITIZER", and "Warning, contains the allergens egg and fish" have been included on the principal display panel of the end-use product labels and "Severely irritating to the eye", "DO NOT get in eyes", "May irritate skin", "Avoid inhaling as a mist or dust on drying, and "May cause sensitization. DO NOT apply if allergic to eggs or fish. DO NOT apply if sensitive or allergic to garlic." have been included in the PRECAUTIONS section of the secondary display panel of both end-use product labels.

Because some individuals may be sensitive to eggs, fish, or garlic, for example, allergic, the statements, "Apply only when the potential for drift is minimal", "Individuals who are sensitive or allergic to eggs, fish, or garlic should avoid handling Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray" and "Individuals who are sensitive or allergic to eggs, fish, or garlic should avoid treated areas have dried or until after a heavy rain" have also been included in the PRECAUTIONS section of the secondary display panel of the product labels.

What Additional Scientific Information Is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of this Evaluation Report or in the Section 12 Notice associated with these conditional registrations. The applicant must submit the following information within the time frames indicated.

Value

Confirmatory efficacy data are required to support the use on herbaceous ornamental species.

Other Information

As these conditional registrations relate to a decision on which the public must be consulted,[3] the PMRA will publish a consultation document when there is a proposed decision on applications to convert the conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

The test data cited in this Evaluation Report (i.e. the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.inforserv@hc-sc.gc.ca).

[3] As per subsection 28(1) of the *Pest Control Products Act*.

Science Evaluation

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

1.1.1 Whole Egg Solids

Active substance	Whole Egg Solids
Function	Animal Repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable
2. Chemical Abstracts Service (CAS)	Not applicable
CAS number	Not applicable
Molecular formula	Not applicable
Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient	Dried Whole Eggs 99%

1.1.2 Bobbex Deer Repellent RTU Technical

Active substance	Wintergreen oil Castor oil Fish meal mixture Fish oil mixture Garlic oil Meat meal mixture
Function	Animal Repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable
2. Chemical Abstracts Service (CAS)	Not applicable
CAS number	Not applicable
Molecular formula	Not applicable

Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient	Wintergreen oil.....9.89% Castor oil.....3.13% Fish meal mixture.....77.08% Fish oil mixture.....3.90% Garlic oil FCC.....0.26% Meat meal mixture.....5.73%

1.1.3 Bobbex Deer Repellent Concentrate Technical

Active substance	Wintergreen oil Castor oil Fish meal mixture Fish oil mixture Garlic oil Meat meal mixture
Function	Animal Repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable
2. Chemical Abstracts Service (CAS)	Not applicable
CAS number	Not applicable
Molecular formula	Not applicable
Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient	Wintergreen oil.....6.22% Castor oil.....3.94% Fish meal mixture.....72.72% Fish oil mixture.....3.69% Garlic oil FCC.....0.33% Meat meal mixture.....13.10%

1.2 Physical and Chemical Properties of the Active Ingredients and End-use Product

1.2.1 Technical Product: Dried Whole Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical

Technical Product—Dried Whole Eggs

Property	Result
Colour and physical state	Yellow course powder
Odour	Egg smell
Melting range	Not applicable. The product is a mixture of complex components
Boiling point or range	Not applicable. The product is a solid
Specific gravity at 20°C	0.3
Vapour pressure at 20°C	Not applicable
Henry's law constant at 20°C	Not applicable
Ultraviolet (UV)-visible spectrum	Not applicable
Solubility in water at 20°C	50 g/100mL
Solubility in organic solvents at 20°C (g/100 mL)	Not available
n-Octanol–water partition coefficient (K_{ow})	Not available
Dissociation constant (pK_a)	Not applicable
Stability (temperature, metal)	Not required. The product is food edible grade.

Technical Product—Bobbex Deer Repellent RTU Technical

Property	Result
Colour and physical state	Not applicable. The product is a mixture of several complex components
Odour	Not applicable. The product is a mixture of several complex components
Melting range	Not applicable. The product is a liquid at room temperature
Boiling point or range	Not applicable. The product is a mixture of several complex components
Density	Not provided
Vapour pressure at 20°C	Not applicable. The product is a mixture of several complex components
Henry's law constant at 20°C	Not applicable

Property	Result
Ultraviolet (UV)-visible spectrum	Not applicable
Solubility in water at 20°C	Not applicable
Solubility in organic solvents at 20°C (g/100 mL)	The product is a mixture of complex components.
n-Octanol–water partition coefficient (K_{ow})	The product is a mixture of complex components.
Dissociation constant (pK_a)	The product is a mixture of complex components.
Stability (temperature, metal)	The product is a mixture of complex components.

1.2.2 End-use Product: Bobbex Deer Repellent Concentrate, Bobbex Deer Repellent Ready-To-Use Spray

End-use Product—Bobbex Deer Repellent Ready-To-Use Spray

Property	Result
Colour	Light brown
Odour	Strong vegetable smell
Physical state	Liquid
Formulation type	Suspension
Guarantee	Whole Egg Solids.....0.93% Capsaicin.....0.001% Related capsaicinoids.....0.001% Wintergreen oil.....0.53% Castor oil.....0.17% Fish meal mixture.....4.09% Fish oil mixture.....0.21% Garlic oil.....0.014% Meat meal mixture.....0.304%
Container material and description	Plastic jug with screw on lid (0.95 and 1.18 L)
Density	1.027 g/cm^3
pH of 1% dispersion in water	3.2 (1% solution)
Oxidizing or reducing action	The product does not contain oxidizing or reducing agents
Storage stability	Stable under ambient conditions
Corrosion characteristics	Not corrosive
Explodability	The product does not contain potentially explosive ingredients

End-use Product—Bobbex Deer Repellent Concentrate

Property	Result
Colour	Light brown
Odour	Strong vegetable smell
Physical state	Liquid
Formulation type	Suspension
Guarantee	Whole Egg Solids.....2.32% Capsaicin.....0.003% Related capsaicinoids.....0.0025% Wintergreen oil.....0.53% Castor oil.....0.33% Fish meal mixture.....6.13% Fish oil mixture.....0.31% Garlic oil.....0.028% Meat meal mixture.....1.10%
Container material and description	Plastic jug with screw on lid (1, 4 and 10 L)
Density	1.027 g/cm^3
pH of 1% dispersion in water	3.85 (1% solution)
Oxidizing or reducing action	The product does not contain oxidizing or reducing agents
Storage stability	Stable under ambient conditions
Corrosion characteristics	Not corrosive
Explodability	The product does not contain potentially explosive ingredients

1.3 Directions for Use

Bobbex Deer Repellent Concentrate must be mixed in a 5:1 dilution with water prior to application to outdoor ornamental plants. Bobbex Deer Repellent Ready-To-Use is already diluted and is applied directly to outdoor ornamental plants without mixing. These products are applied until wet. If a risk of feeding damage by deer persists, the products can be re-applied after 28 days for conifers and 14 days for all other ornamentals. In heavily browsed areas, the products can be re-applied sooner and new growth should always be sprayed.

1.4 Mode of Action

The mixture of whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids repel deer by both taste and odour.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

All the active ingredients are mixtures of complex components and therefore no analytical method to determine the composition of this product is required.

2.2 Method for Formulation Analysis

All the active ingredients except for capsaicin and related capsaicinoids are mixtures of complex components and, therefore, no analytical enforcement method is required. An official (AOAC) analytical enforcement method for capsaicin and related capsaicinoids is already on file.

3.0 Impact on Human and Animal Health

3.1 Integrated Toxicology Summary

The PMRA conducted a detailed review of publicly available information on the toxicology of whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids. Overall, the scientific quality of the available information is acceptable and the database is sufficiently complete to define the majority of the toxic effects that may result from exposure to whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids when they are applied together as a pest control product.

Based on a long history of safe consumption of eggs as a food, the anticipated acute oral, dermal, and inhalation toxicity is expected to be low, and the primary skin and eye irritation negligible. As eggs are known to cause allergic reactions in certain sensitive individuals, the product is assumed to be a potential sensitizer. The information summarized in Appendix I, Table 1 was used to assess the toxicological effects of both the technical product, Dried Whole Eggs, and the end-use products, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray.

Capsaicin is a registered active ingredient that has undergone re-evaluation by the PMRA (Re-evaluation Decision Document RRD2004-30, *Capsaicin*) and there are no outstanding toxicological issues or concerns related to this ingredient when used as an animal and area repellent similar to the uses for Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray.

Both end-use products contain the active ingredients wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture. Each of these ingredients is permitted in other pesticide formulations as formulants rather than as active ingredients, except for garlic oil which was recently approved by PMRA as an active ingredient for use in an area repellent against deer. These substances were classified as active ingredients in the Bobbex end-use products because they are known to repel deer and, therefore, contribute to the overall mode of action of the end-use products whereas formulants do not contribute to the targeted activity of

the product. As formulants, these ingredients are either of minimal toxicological concern (List 4A) or of minimal concern under specific conditions of use (List 4B). Since the use pattern of the end-use products does not constitute a unique use for the active ingredients that are also List 4B formulants, no additional information was required to assess the toxicological hazards of these active ingredients. The anticipated acute oral, dermal, and inhalation toxicity of these active ingredients is expected to be low, and the primary skin and eye irritation negligible. However, the active ingredients which are derived from fish and garlic are of toxicological concern as they are known allergens.

Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray both contain capsaicin and other ingredients i.e., wintergreen oil, castor oil, fish oil and garlic oil which are known to irritate the skin, eyes and upper respiratory tract on contact.

Based on the long history of safe consumption of whole eggs as food and the minimal toxicological concern of the other active ingredients, the PMRA did not require submission of additional toxicological test data.

3.2 Occupational/Residential Exposure and Risk Assessment

Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray are intended to repel white tail and black tail mule deer from around domestic settings and are to be applied only to ornamental plants, including trees, shrubs, flowers, and non-flowering plants.

A 28 day reapplication period is on both end use products.

3.2.1 Occupational/Domestic-user

Exposure to Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray is expected to be short-term in duration and predominantly by the dermal route. Inhalation, accidental ingestion, and dermal or ocular exposure to the end-use products are also possible during product application, but are likely to be only minor routes of exposure. Although a margin of exposure could not be estimated based on the toxicological information available, exposure to the end-use product, when label instructions and precautions are observed, is not expected to pose a health concern.

The risk from dermal and inhalation exposure of the applicator to whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids is anticipated to be negligible. The PMRA requires users to follow precautionary label statements aimed at mitigating exposure such as only applying the product where the possibility of drift is minimal, and for individuals who are sensitive to eggs, garlic or fish to avoid handling the end-use products and avoid entering treated areas until residues have dried.

3.2.2 Bystander

Bystander exposure from the domestic application of Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray is expected to be minimal and of short-term duration based on the methods of application and adherence to use precautions. This transient exposure is not expected to pose a health risk for individuals who are not sensitive to eggs, fish, or garlic.

Accidental bystander exposure is possible from spray drift, resulting in inhalation, dermal, and ocular exposure. However, when the end-use products are used as directed, bystander exposure is expected to be minimal and not of concern.

Postapplication activities are expected to be typical of a residential setting, thus postapplication exposure to adults, and children is likely. Individuals with sensitivities to egg, fish, or garlic should avoid treated areas until residues have dried.

3.3 Food Residue Exposure Assessment

Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray are not intended for application to food or feed crops. Consequently, the risk from dietary exposure from whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids is considered negligible.

3.4 Aggregate Exposure

The potential for exposure of the general public to whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids resulting from use of the end-use products as a deer repellent is not expected to be of concern, considering the natural occurrence of these substances and their current uses in foods and other consumer products. Exposure via drinking water is not expected to occur from the use on ornamentals, including trees, shrubs, flowers, and non-flowering plants. Consequently, an aggregate exposure assessment was not conducted by the PMRA.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids are food grade biological substances, and rapid degradation in the environmental is expected to occur through normal biological, physical, and chemical processes.

4.2 Environmental Risk Characterization

Based on limited exposure, the biological nature of the chemicals, and the likelihood for relatively rapid transformation under environmental conditions, the use of whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids are not expected to pose a risk to the environment under the use pattern. Therefore, further review of any environmental chemistry, fate, and toxicology of whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids was not considered necessary.

5.0 Value

5.1 Effectiveness Against Pests

An efficacy trial conducted in spring 2006 in Washington demonstrated that Bobbex Deer Repellent Concentrate applied at a 5:1 dilution repelled both white-tailed deer and black-tailed deer from Western red cedar and Douglas fir seedlings for up to 28 days. The efficacy of Bobbex Deer Repellent Concentrate was similar to the efficacy of the commercial standard containing dried blood in this trial. Most of the untreated plants were completely defoliated by the end of the trial as a result of browsing by deer. The efficacy of Bobbex Deer Repellent Ready-To-Use is expected to be similar to that of Bobbex Deer Repellent Concentrate.

Two efficacy trials (1 on rosebushes and 1 on hydrangeas) conducted in Washington and Victoria, British Columbia in spring 2005 suggested that Bobbex Deer Repellent Concentrate applied at a various concentrations repelled white-tailed deer for up to 14 days. Given the mode of action of this product (i.e., taste and odour repellent) and non-conventional status, it is likely that the product would repel white-tailed and black-tailed deer on other ornamentals.

Confirmatory efficacy data are required to support the use on herbaceous ornamental species.

5.1.1 Acceptable Efficacy Claims

Bobbex Deer Repellent Concentrate at a dilution of 1 part product to 5 parts water and Bobbex Deer Repellent Ready-To-Use to prevent feeding damage to outdoor ornamental plants by white-tailed and black-tailed deer.

5.2 Phytotoxicity to Host Plants

5.2.1 Acceptable Claims for Host Plants

No phytotoxicity or brown-off was noticed or recorded on any of the plants treated with Bobbex Deer Repellent Concentrate during the trial. However, given the number of potential ornamental plant species and cultivars to be treated with Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use, it is recommended that a small number of plants be treated prior to applying to a large area to test for potential phytotoxic effects.

5.3 Sustainability

Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use act as a repellent and thus, does not kill the deer.

5.3.1 Survey of Alternatives

There are several pest control products containing different active ingredients used to repel deer from plants including putrescent whole egg solids, thiram, denatonium benzoate and dried blood. Excluding the animal by using fencing, growing plants which deer do not like to consume and the presence of dogs may also be effective alternatives to prevent deer damage to outdoor ornamental plants.

5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management

Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use are compatible with many of the pest control alternatives indicated in Section 5.5.1.

5.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Resistance is not expected to occur. However, deer may eat treated plants when alternative food sources are scarce and if the same repellent is used repeatedly. To prevent deer from becoming accustomed to a specific repellent, it is recommended that different repellents be used periodically.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids and their transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[4] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids do not meet the Track 1 criteria and will not form any transformation products which meet the Track 1 criteria. Whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids are naturally occurring substances and are not expected to be persistent or bioaccumulative in the environment.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[5] The list is used as described in the PMRA Notice of Intent NOI2005-01[6] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[7] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Dried Whole Eggs, Capsaicin, Bobbex Deer Repellent Ready-To-Use Technical, Bobbex Deer Repellent Concentrate Technical, and the end-use products Bobbex Deer Repellent Ready-To-Use Spray and Bobbex Deer Repellent Concentrate do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

- The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

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4 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

5 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

6 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

7 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

7.0 Summary

7.1 Human Health and Safety

The available toxicological information on whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids is adequate to identify the majority of toxic effects that may result from exposure to the active ingredients. Eye and skin irritation is possible, as well as allergic reactions in individuals sensitive to eggs, fish, or garlic. No other toxicologically significant effects were reported in available information on whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids.

The precautionary statements on the product labels are adequate to protect applicators and bystanders. The product label instructs domestic users to not apply Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray if there is the potential for spray drift from targeted areas. Judicious application of the product is not expected to result in applicators being exposed to concentrations of egg, fish, or garlic that would be of concern. Furthermore, allowing Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray to dry after each application will ensure that bystanders and pets are unlikely to come in contact with eggs, fish, or garlic at concentrations that would be of concern.

Because Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray are not to be applied to food or feed crops, the establishment of a maximum residue limit was not required for whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids

Individuals who are allergic to eggs, fish, or garlic are advised to avoid handling Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray, as well avoid entering treated areas until sprayed residues have dried completely.

7.2 Environmental Risk

Based on limited exposure, the chemical's natural occurrence and the likelihood for relatively rapid transformation under environmental conditions, the use of whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids are not expected to pose a significant risk to the environment.

7.3 Value

Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use repel white-tailed and black-tailed deer on conifers for up to 28 days and up to 14 days for other outdoor ornamental plants.

7.4 Unsupported Uses

All proposed uses were accepted.

8.0 Regulatory Decision

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Dried Whole Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray containing the active ingredients Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids to prevent feeding damage to outdoor ornamental plants by white-tailed deer and black-tailed deer.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of this Evaluation Report or in the Section 12 Notice associated with these conditional registrations.

NOTE: The PMRA will publish a consultation document at the time when there is a proposed decision on applications to convert these conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

Value

Confirmatory efficacy data are required testing Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use on herbaceous ornamental plants species to prevent feeding damage to outdoor ornamentals by white-tailed and black-tailed deer.

List of Abbreviations

CAS	Chemical Abstracts Service
EP	end-use product
g	gram
kg	kilogram
K_{ow}	*n*-octanol–water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
m^3	metre(s) cubed
mg	milligram
mm	millimetre(s)
N/A	not applicable
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Acute Toxicity of Technical Products Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil and Meat Meal Mixture and the Associated End-use Products (Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray)

Acute Toxicity of Whole Egg Solids (Technical)	
Oral	The data requirements were waived on the basis of a long history of safe consumption of eggs as a whole foodstuff.
Dermal	
Inhalation	
Skin irritation	
Eye irritation	
Skin sensitization	Eggs are a confirmed allergen and exposure may result in an allergic reaction in sensitive individuals.
Acute Toxicity of Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil and Meat Meal Mixture (Technical)	
Oral	The data requirement s were waived on the basis that all of the components in the Active Ingredient Mixture are on PMRA's Formulant List 4A (Minimal Toxicological Concern) or List 4B (Minimal Concern Under Specific Conditions of Use) and are foods or food additives.
Dermal	
Inhalation	
Skin irritation	
Eye irritation	
Skin sensitization	Fish and garlic are confirmed allergens. Exposure may result in an allergic reaction in sensitive individuals.
Acute Toxicity of End-use Product – Bobbex Deer Repellent Concentrate	
Oral	The data requirements were waived on the basis of a long history of safe consumption of eggs as a whole foodstuff and that there does not appear to be any components of the formulation that, when exposed to in an acute manner will result in lethality in individuals who are not sensitive to fish or garlic.
Dermal	
Inhalation	
Skin irritation	Capsaicin, wintergreen oil, castor oil, fish oil and garlic oil are present in the end-use product. Dermal exposure may result in irritation to the skin.
Eye irritation	Capsaicin, wintergreen oil, castor oil, fish oil and garlic oil are present in the end-use product. Ocular exposure may result in irritation to the eyes.
Skin sensitization	The end-use product contains formulants derived from fish and garlic, as well as containing eggs as the active ingredient. Both eggs and fish are confirmed allergens. Also, exposure to formulants derived from garlic may result in an allergic reaction in sensitive individuals.

Acute Toxicity of End-Use Product – Bobbex Deer Repellent Ready-To-Use Spray	
Oral	The data requirements were waived on the basis of a long history of safe consumption of eggs as a whole foodstuff and that there does not appear to be any components of the formulation that, when exposed to in an acute manner will result in lethality in individuals who are not sensitive to fish or garlic.
Dermal	
Inhalation	
Skin irritation	Capsaicin, wintergreen oil, castor oil, fish oil and garlic oil are present in the EP. Dermal exposure may result in irritation to the skin.
Eye irritation	Capsaicin, wintergreen oil, castor oil, fish oil and garlic oil are present in the EP. Ocular exposure may result in irritation to the eyes.
Skin sensitization	The end-use product contains formulants derived from fish and garlic, as well as containing eggs as the active ingredient. Both eggs and fish are confirmed allergens. Also, exposure to formulants derived from garlic may result in an allergic reaction in sensitive individuals.

Table 2 Toxicity Profile of Technical Whole Egg Solids

Study Type	Species	Results (mg/kg/day in M/F)	Reference
90-day dietary	The data requirements for short-term toxicity, prenatal developmental toxicity, and genotoxicity were waived on the basis of a long history of safe consumption of eggs as a whole foodstuff.		
Prenatal Developmental toxicity			
Reverse gene mutation assay			
Gene mutations in mammalian cells in vitro			

Table 3 Toxicity Profile of Technical Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil and Meat Meal Mixture

90-day dietary	The data requirements for short-term toxicity, prenatal developmental toxicity, and genotoxicity were waived on the basis that all of the components in the Active Ingredient Mixture are on PMRA's Formulant List 4A (Minimal Toxicological Concern) or List 4B (Minimal Concern Under Specific Conditions of Use) and are foods or food additives.
Prenatal Developmental toxicity	
Reverse gene mutation assay	
Gene mutations in mammalian cells in vitro	

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

1749988 Chemistry Data - TGAI Eggs, DACO: 2.0 **CBI**
1749989 Report of NorthEast Laboratories, DACO: 2.16 **CBI**
1852601 2009, Part 2 Chemistry Requirements, DACO: 2.0 **CBI**
1750082 Chemistry requirements for TGAI Eggs, DACO: 2.0 **CBI**
1750084 Chemistry requirements for Safener - Liquid Fish Emulsion (Manheden), DACO: 2.0 **CBI**
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1750086 Chemistry requirements for Safener - spike, DACO: 2.0 **CBI**
1750087 2009, Chemistry requirements for EP Bobbex RTU, DACO: 3.0 **CBI**
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1750035 Lab Report - Eggs, DACO: 2.14 **CBI**
1750037 Chemistry requirements for Safener - Liquid Fish Emulsion (Manheden), DACO: 2.0 **CBI**
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1750041 2009, Chemistry requirements for Safener MGSO4 analysis, DACO: 2.0 **CBI**
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1750045 Product analysis - enforcement analytical method, DACO: 3.1, 3.2, 3.2.1, 3.2.2, 3.4.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 **CBI**
1750046 Physical properties analysis of Bobbex EP Concentrate, DACO: 3.5 **CBI**
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2.0 Human and Animal Health

PMRA Document Number	**Reference**
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1749991	Toxicology Acute Studies - Eggs (TGAI) - WAIVER REQUEST, DACO: 4.1
1750047	Summary of toxicology profile, DACO: 4.1,4.6
1750048	2009, EP Toxicology report from Michigan State, DACO: 4.6
1750049	Summary of occupational and bystander exposure - Bobbex (EP), DACO: 5.1,5.2
1750089	Summary of toxicology profile, DACO: 4.1,4.6
1750090	Summary of occupational and bystander exposure - Bobbex (EP), DACO: 5.1,5.2

3.0 Value

1750051 Value summary, DACO: 10.1,10.2.2,10.2.3.1,10.2.3.3,10.3.1,10.3.2

1750053 2006, Efficacy of a New Formulation of Bobbex Brand Deer Repellent, DACO: 10.2.3.3

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1750055 2005, Efficay trial for Bobbex Deer Repellent May - June 2005, Sequim, WA, DACO: 10.2.3.3

1750056 PRT Campbell River Nursery Ungulate Repellent Research Fall 2005, DACO: 10.2.3.3

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1750058 2009, Efficacy: Operational Trials Evaluation Template, DACO: 10.2.3.4

1767004 Mode of action, DACO: 10.2.1

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